510(K) SUMMARY

S2000 Diagnostic Ultrasound system

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**

Siemens Medical Solutions USA, Inc., Ultrasound Division
1230 Shorebird Way
Mountain View, CA 94043

Contact Person:
Shelly Pearce
Regulatory Affairs

Phone: (650) 694-5988
FAX: (650) 943-7053

NOV 1 3 2007

Date Prepared:
September 4, 2007

2. **Proprietary Name:**
Acuson S2000™ Diagnostic Ultrasound System

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:
21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX

3. **Predicate Device:**
K063803, 11/22/2006, Acuson Antares Diagnostic Ultrasound System
K063085, 11/14/2006, Acuson Sequoia Diagnostic Ultrasound System
K032620, 10/10/2003, GE Voluson 730 Ultrasound System

4. **Device Description:**
The Acuson S2000™ Ultrasound System is a new multi-purpose mobile, software controlled diagnostic ultrasound system with and on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D/4D Imaging on a Flat Panel Display.

The S2000, has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound

- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
  - EN 60601-2-37
- IEC 61157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

5. Intended Uses:

The S2000 ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, Fetal, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Pediatric, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Comparison to Predicate Device:

The S2000 is substantially equivalent to the Acuson Antares, cleared via K063803, the Acuson Sequoia, cleared via K063085, and the GE Voluson, cleared via K032620. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2007

Siemens Medical Solutions USA, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K072786
Trade/Device Name: Acuson S2000™ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 29, 2007
Received: October 1, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson S2000™ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CW2 Probe	4P1 Phased Array
CW5 Probe	6C2 Curved Array
9EC4 Curved Array	4C1 Curved Array
9L4 Linear Array	4V1 Phased Array
14L5 Multi-D Array	10V4 Phased Array

14L5 SP Linear Array	V5Ms Multiplane TEE
7CF2 Curved Array	17L5HDS Linear Array
9EVF4 Curved Array	8V3 Phased Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): K072786

Device Name: Acuson S2000™ Diagnostic Ultrasound System

Indications for Use:

The S2000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Prescription Use XX (Part 21 CFR 801 Subpart D) OR Over-the-Counter-Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072786

K072786

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **ACUSON S2000 Ultrasound System**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Abdominal		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Intraoperative (Note 9)		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Intraoperative Neurological		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Pediatric		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,10
Cardiac		N	N	N	N	N	N		BMDC	Note 2,3,4,5,6,7,8,10
Trans-esophageal		N	N	N	N	N	N		BMDC	
Transrectal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10, 11,14
Transvaginal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral										
Intravascular										
Peripheral vessel		N	N	N	N	N	N		BMDC	Note2,3,4,5,6,7,8,10, 11,14
Laparoscopic										
Musculo-skeletal Conventional		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,10, 11,14
Other (specify) Neonatal Cardiac		N	N	N	N	N	N		BMDC	Note 3,4,6

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 9 For example: vascular, abdominal
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 13 STIC
Note 14 eSie™ Touch elasticity imaging/FTI

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072786

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Prescription Use (Per 21 CFR 801.10
Diagnostic Ultrasound Indications for Use Form

K072786

510 (k) Number (if known):

Device Name: **CW2 Probe for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					P					
Abdominal					P					
Intraoperative (Note 9)					P					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial					P					
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 9 For example: vascular, abdominal

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072786

K072786

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **CW5 Probe for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					P					
Abdominal					P					
Intraoperative (Note 9)					P					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial					P					
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 9 For example: vascular, abdominal

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072786

K072786

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **9EC4 Curved Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,6,,7,8,10, 11
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 14 eSie™ Touch elasticity imaging/FTI

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072786

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Prescription Use (Per 21 CFR 801.109)

K072786

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **9L4 Linear Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 14 eSie™ Touch elasticity imaging/FTI

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Prescription Use (Per 21 CFR 801.109)

K072786

Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **14L5 Multi-D Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,6, 7,8,10, 11, 14
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 14 eSie™ Touch elasticity imaging/FTI

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Prescription Use (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **4P1 Phased Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8,10
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072786

K072786

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **6C2 Curved Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding

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Prescription Use (Per 21 CFR 801.109)

K072786

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **4C1 Curved Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P		P	P		BMDC	Note2,3,4,5,6,7,8, 10, 11
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **4V1 Phased Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10,
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **10V4 Phased Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 3,4
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **14L5 SP Linear Array Transducer for use with ACUSON S2000**
Indications For Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 9)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note2,3,4,5,6 ,7,8,10, 11,14
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 9 For example: vascular, abdominal
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 14 eSie™ Touch elasticity imaging/FTI

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **7CF2 Curved array mechanical 3D transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,13
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 13
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 13 STIC

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **9EVF4 Curved Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8, 10,11
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8, 10,11
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8, 10,11
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **V5Ms Multiplane TEE Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	P	P	P	P	P		BMDC	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803; E = added under Appendix E

Additional Comments: n/a

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **17L5HDS Linear Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 14 eSie™ Touch elasticity imaging/FTI

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **8V3 Phased Array Transducer for use with ACUSON S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 3,4,6
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		P	P	P	P	P	P		BMDC	Note 3,4,6

N = new indication; P = previously cleared by FDA K# 063085; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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